



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification: A61B 17/32	A1	(11) International Publication Number: WO 97/42886 (43) International Publication Date: 20 November 1997 (20.11.97)
--	-----------	---

(21) International Application Number: PCT/US97/08402

(22) International Filing Date: 16 May 1997 (16.05.97)

(30) Priority Data:

60/017,133	17 May 1996 (17.05.96)	US
60/019,918	14 June 1996 (14.06.96)	US
60/023,658	1 August 1996 (01.08.96)	US
60/025,340	3 September 1996 (03.09.96)	US
08/714,548	16 September 1996 (16.09.96)	US
08/710,456	17 September 1996 (17.09.96)	US
08/727,074	8 October 1996 (08.10.96)	US

(71) Applicant: MERCURY DIAGNOSTICS, INC. [US/US]; Suite D, 1137 San Antonio Road, Palo Alto, CA 94303 (US).

(72) Inventors: DUCHEN, Brent, G.; 410 Milan Drive #106, San Jose, CA 95134 (US). DOUGLAS, Joel, S.; 2048 Calabazas Boulevard, Santa Clara, CA 95051 (US). ROE, Jeffrey, N.; 3212 Veracruz Drive, San Ramon, CA 94583 (US). RADWANSKI, Ryszard; 16830 Sundance Drive, Morgan Hill, CA 95037 (US). DREXLER, Andrew, M.; 12580 La Cresta Drive, Los Altos Hills, CA 94022 (US).

(74) Agents: DILLAHUNTY, T., Gene et al.; Burns, Doane, Swecker & Mathis, L.L.P., P.O. Box 1404, Alexandria, VA 22313-1404 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

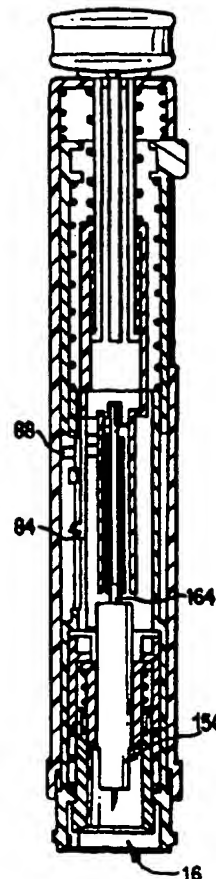
Published

With international search report.

(54) Title: BODY FLUID SAMPLING DEVICE AND METHODS OF USE

(57) Abstract

A device for sampling body fluid includes a housing (12) having a sleeve (102) at a forward end thereof which is displaceable in response to being pressed against a user's skin to trigger the firing of a lancet (150). After the lancet (150) is removed from the incision, the sleeve (102) is repeatedly pressed against the skin to depress a ring of body tissue in surrounding relationship to the incision to express body fluid outwardly through the incision. A pusher member (24) is then actuated to push a capillary tube (164) through a front end of the housing for drawing in body fluid. The lancet (150) is a disposable lancet which includes a body supporting a skin lancing member (154) and the capillary tube (164). The disposable lancet (150) passes through an upper end of a lancet carrier (16) when being installed or removed. The device cannot be armed until the disposable lancet (150) is installed in the housing (12), because the capillary tube (164) functions to push a safety device to a non-safety position.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

BODY FLUID SAMPLING DEVICE AND METHODS OF USE

Field of the Invention

The present invention relates to lancing devices and methods for obtaining samples of blood and other
5 fluids from the body for analysis or processing.

Background of the Invention

Many medical procedures in use today require a relatively small sample of blood, in the range of 5-50 μ L. It is more cost effective and less traumatic to the
10 patient to obtain such a sample by lancing or piercing the skin at a selected location, such as the finger, to enable the collection of 1 or 2 drops of blood, than by using a phlebotomist to draw a tube of venous blood. With the advent of home use tests such as self monitoring of blood
15 glucose, there is a requirement for a simple procedure which can be performed in any setting by a person needing to test.

Lancets in conventional use generally have a rigid body and a sterile needle which protrudes from one
20 end. The lancet may be used to pierce the skin, thereby enabling the collection of a blood sample from the opening created. The blood is transferred to a test device or collection device. Blood is most commonly taken from the fingertips, where the supply is generally excellent.
25 However, the nerve density in this region causes significant pain in many patients. Sampling of alternate site, such as earlobes and limbs, is sometimes practiced to access sites which are less sensitive. These sites are also less likely to provide excellent blood samples and
30 make blood transfer directly to test devices difficult.

Repeated lancing in limited surface areas (such as fingertips) results in callous formation. This leads to increased difficulty in drawing blood and increased pain.

To reduce the anxiety of piercing the skin and the associated pain, many spring loaded devices have been developed. The following two patents are representative of the devices which were developed in the 1980's for use with home diagnostic test products.

Cornell et al. U.S. Patent No. 4,503,856 describes a spring loaded lancet injector. The reusable device interfaces with a disposable lancet. The lancet holder may be latched in a retracted position. When the user contacts a release, a spring causes the lancet to pierce the skin at high speed and then retract. The speed is important to reduce the pain associated with the puncture.

Levin et al. U.S. Patent No. 4,517,978 describes a blood sampling instrument. This device, which is also spring loaded, uses a standard disposable lancet. The design enables easy and accurate positioning against a fingertip so the impact site can be readily determined. After the lancet pierces the skin, a bounce back spring retracts the lancet to a safe position within the device.

In institutional settings, it is often desirable to collect the sample from the patient and then introduce the sample to a test device in a controlled fashion. Some blood glucose monitoring systems, for example, require that the blood sample be applied to a test device which is in contact with a test instrument. In such situations, bringing the finger of a patient directly to the test device poses some risk of contamination from blood of a previous patient. With such systems, particularly in hospital settings, it is common to lance a patient, collect a sample in a micropipette via capillary action and then deliver the sample from the pipette to the test device.

Haynes U.S. Patent No. 4,920,977 describes a blood collection assembly with lancet and microcollection

tube. This device incorporates a lancet and collection container in a single device. The lancing and collection are two separate activities, but the device is a convenient single disposable unit for situations when sample collection prior to use is desirable. Similar devices are disclosed in Sarrine U.S. Pat. No. 4,360,016, and O'Brien U.S. Pat. No. 4,924,879.

Jordan et al. U.S. Patents No. 4,850,973 and No. 4,858,607, disclose a combination device which may be alternatively used as a syringe-type injection device and a lancing device with disposable solid needle lancet, depending on configuration.

Lange et al. U.S. Patent No. 5,318,584 describes a blood lancet device for withdrawing blood for diagnostic purposes. This invention uses a rotary/sliding transmission system to reduce the pain of lancing. The puncture depth is easily and precisely adjustable by the user.

Suzuki et al. U.S. Patent No. 5,368,047, Dombrowski U.S. Patent No. 4,654,513 and Ishibashi et al. U.S. Patent No. 5,320,607 each describe suction-type blood samplers. These devices develop suction between the lancing site and the end of the device when the lancet holding mechanism withdraws after piercing the skin. A flexible gasket around the end of the device helps seal the end around the puncture site until adequate sample is drawn from the puncture site or the user pulls back on the device.

Garcia et al. U.S. Patent No. 4,637,403 and Haber et al. U.S. Patent No. 5,217,480, disclose combination lancing and blood collection devices which use a diaphragm to create a vacuum over the wound site.

Erickson et al. U.S. Patent No. 5,582,184 describes a means of collecting and measuring body fluids.

This system uses a coaxial syringe and capillary tube disposed within a spacer member. The spacer member limits the depth of syringe penetration, and compresses body tissue around the syringe while the syringe is in the skin, for improving the flow of interstitial fluid to the incision. However, it will be appreciated that the incision will tend to close against the syringe, thereby limiting any advantage that can be achieved.

Single use devices have also been developed for single use tests, i.e. home cholesterol testing, and for institutional use to eliminate cross-patient contamination multi-patient use. Crossman et al. U.S. Patent No. 4,869,249, and Swierczek U.S. Patent No. 5,402,798, also disclose disposable, single use lancing devices.

U.S. Patents 5,421,816; 5,445,611; and 5,458,140 disclose, as a replacement for invasive sampling, the use of ultrasound to act as a pump for expressing interstitial fluid directly through intact (non-lanced) skin. The amount of fluid which can be obtained in that way is very limited, however.

The disclosures of the above patents are incorporated herein by reference.

Even with the many improvements which have been made, the pain associated with lancing remains a significant issue for many patients. The need for blood sampling and the fear of the associated pain is also a major obstacle for the millions of diagnosed diabetics, who do not adequately monitor their blood glucose due to the pain involved. Moreover, lancing to obtain a blood sample for other diagnostic applications is becoming more commonplace, and a less painful, minimally invasive device is needed to enhance those applications and make those technologies more acceptable.

An object of the present invention therefore, is to provide a device and a method for obtaining a sample of bodily fluid through the skin which is virtually pain free and minimally invasive.

5 Furthermore, known lancing devices include manually actuatable buttons for triggering the lance-driving mechanism once the user has placed the device against his/her skin. Because the user knows the precise instant when the lancet will be triggered, there is a tendency for
10 the user to jerk or raise the device at the instant of triggering, which can lead to inconsistent skin penetration, or possibly no penetration. Therefore, a further object of the invention is to provide a lancing device which eliminates such a tendency on the part of the
15 user.

Moreover, known carriers for supporting disposable lancets are configured to permit the disposable to be inserted and removed solely through a lower end thereof. That requires that a user grasp a lower portion
20 of the disposable in order to push it upwardly or pull it downwardly. Since the needle projects from a lower end of the disposable, the user's hand will be in the immediate vicinity of the needle, and thus exposed to potential injury and/or contamination. Also, the disposable is
25 typically held in the carrier by friction fit. Due to normal manufacturing tolerances, it is difficult to ensure a sufficiently tight fit for the disposable; there may be a tendency for the disposable to wobble, thereby increasing the amount of pain inflicted during a lancing
30 step.

Therefore, it is another object of the invention to provide a lancet carrier which eliminates the above-mentioned shortcomings.

35 An additional object of the invention is to make a lancing device safer by preventing the lancet-driving

mechanism from being cocked until the disposable has been inserted therein.

Another object of this invention is to provide a method which can result in a sample of either blood or interstitial fluid, depending on the sample site and the penetration depth utilized. While there are no commercially available devices utilizing interstitial fluid (ISF) at this time, there are active efforts to establish the correlation of analytes, such as glucose, in ISF compared to whole blood. If ISF could be readily obtained and correlation is established, ISF may be preferable as a sample since there is no interference of red blood cells or hematocrit adjustment required.

Another object of this invention is to provide a method which can draw a small but adjustable sample, i.e. 3 μ L for one test device and 8 μ L for another test device, as appropriate.

Another object of this invention is to provide a method by which the drawn sample is collected and may be easily presented to a testing device, regardless of the location of the sample site on the body. This approach helps with infection control in that multiple patients are not brought in contact with a single test instrument; only the sampling device with a disposable patient-contact portion is brought to the test instrument. Alternatively, the disposable portion of a test device may be physically coupled with the sampler so the sample can be brought directly into the test device during sampling. The test device may then be read in a test instrument if appropriate or the testing system can be integrated into the sampler and the test device can provide direct results displayed for the patient.

It is a further object of the invention is to provide a device for minimally invasive sampling

7.

comprising a reusable sampler and disposable lance, and sample collection device.

Summary of the Invention

One aspect of the present invention involves
5 a lancing device for lancing skin to sample blood or interstitial fluid. The device comprising a housing. A lancet carrier is mounted adjacent a front end of the housing for longitudinal movement relative thereto. A cockable spring-biased hammer mechanism is provided for
10 pushing the lancet carrier forwardly to lance the skin. A latch is provided for releasably retaining the hammer mechanism in a cocked position. A latch-releasing mechanism includes a skin-contacting portion for being rearwardly displaced in response to being pressed against
15 the skin, and a latch-releasing portion for releasing the latch in response to the rearward displacement of the skin contacting portion.

In another aspect of the invention, a safety mechanism is provided which is normally disposed in a
20 safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

In another aspect of the invention, a disposable
25 lancet comprises a body which houses a skin lancing member and a capillary tube. A pusher member is provided for pushing the capillary tube forwardly relative to the body after the skin has been lanced, for drawing-in fluid from the lanced skin.

30 Yet another aspect of the invention relates to the combination of a disposable lancet and a carrier therefor. The carrier comprises a sleeve adapted to be mounted in a housing. The sleeve includes an internal surface forming a through passage extending from an upper

end to a lower end of the sleeve. The disposable lancet is seated in the through passage. The internal surface is configured to permit insertion and removal of the disposable lancet solely through the upper end. The internal surface includes at least one upwardly facing shoulder on which the disposable lancet is supported. The invention also relates to the lancet carrier *per se*.

Another aspect of the invention relates to a sampling device for sampling body fluid. The sampling device comprises a housing defining a longitudinal axis, and an incision-forming means for forming an incision through the skin surface. A stimulator member is mounted at a forward end of the housing and is depressible against the skin to depress a ring of body tissue in surrounding relationship to the skin for urging body fluid toward and outwardly through the incision, to form a drop of body fluid at an open end of the incision. A pusher member is provided for moving the capillary tube forwardly relative to the carrier for drawing-in the body fluid.

A method aspect of the invention involves the steps of abutting a forward end of a housing against a skin surface of a user's body, and forming an incision through the skin surface. The housing is pressed against the skin surface to repeatedly depress a ring of body tissue in surrounding relationship to the incision to urge body fluid toward and outwardly through the incision to form a drop of body fluid at an open end of the incision. The capillary tube is extended forwardly relative to the carrier, and a forward end of the capillary tube is inserted into the drop of body fluid.

Brief Description of the Drawings

The objects and advantages of the invention will become apparent from the following detailed description.

of a preferred embodiment thereof in connection with the accompanying drawing in which like numerals designate like elements and in which:

5 Fig. 1 is a side elevational view of a lancing device according to the present invention;

Fig. 2 is a side elevational view of a disposable being inserted into a lancet carrier unit, with the lancet carrier unit being shown in longitudinal section;

10 Figs. 3A-3H are longitudinal sectional views taken through the lancing device and depicting the device in various stages of operation;

Fig. 4 is a longitudinal sectional perspective view of the lancing device according to the invention;

15 Fig. 5 is a bottom perspective view of a pusher member according to the invention;

Fig. 6 is a bottom perspective view of an adapter member according to the present invention;

Fig. 7 is a bottom perspective view of a hammer member according to the present invention;

20 Fig. 8 is another bottom perspective view of the hammer member depicted in Fig. 7;

Fig. 9 is a perspective view of one-half of a housing part according to the present invention;

25 Fig. 10 is a perspective view of the other housing part according to the invention;

Fig. 11 is a perspective view of a disposable according to the invention, with a capillary tube shown in phantom;

30 Fig. 12 is a bottom perspective view of an interposer member according to the present invention;

35 Fig. 13 is a side elevational view of a disposable carrier member according to the present invention, with projections of a disposable shown in phantom lines when the disposable is in an installed condition;

Fig. 14 is a side elevational view, taken from another angle, of the disposable carrier shown in Fig. 13;

Fig. 15 is a sectional view taken through the carrier member of Fig. 13; and

5 Fig. 16 is a bottom perspective view of the carrier of Fig. 13.

Detailed Description of a Preferred Embodiment of the Invention

10 A minimally invasive sampling device 10 shown in Fig. 1, includes a tubular housing 12 formed of two half-shells 12A, 12B (see Figs. 9 and 10) that are secured together. The housing 12 defines a longitudinal axis A and a lower open end 14 adapted to receive a removable lancet carrier unit 16. That carrier unit serves to
15 carry a disposable lancet member 150 (hereinafter a "disposable") and to stimulate a skin puncture site, as will be explained subsequently.

Also mounted in the housing 12 (see Fig. 3A) are a hammer 18 for displacing the disposable downwardly in a
20 skin-piercing direction, a manual handle 20 for raising the hammer to a cocked (i.e., downwardly biased) position, an imposer 22 for automatically releasing the hammer in response to a manual pushing of the device against a skin surface, a manually actuable pusher 24 for pushing a
25 blood-receiving capillary tube downwardly, and a plurality of springs for achieving proper placement and movement of the above-described parts.

The interposer 22, shown in Figs. 3 and 12, is longitudinally movable in the housing 12 and includes
30 lower and upper cylindrical portions 30, 32, the lower portion being of smaller diameter than the upper portion to form an upwardly facing shoulder 34. A pair of diametrically opposed slits 36 is formed in the lower portion 30 for enabling the carrier unit 16 to be slid
35 upwardly into the housing 12.

Formed in the upper portion 32 is a slot 40 through which project three longitudinally parallel guide ribs 42 (see Fig. 10) that are formed integrally with the inner surface of the housing shell 12B. A center one of the ribs 42 is shorter than the other two ribs 42 to form therewith a space into which an end of a capillary tube 164 can fit, as will be explained. Spaced ninety degrees from the slot 40 is another slot 44, and formed on a wall of that slot 44 is a triggering protrusion 46 having an inclined upper cam surface 47, which serves to release the hammer 18 from a cocked position as will be explained.

A coil compression spring 45 is disposed between an upper end of the interposer 22 and shoulders 47 formed on the pusher 24 to bias the interposer 22 downwardly.

The pusher 24, shown in Fig. 5, is longitudinally movable and includes a semi-cylindrical portion 50 having a knob 52 projecting radially outwardly from an upper end thereof. The knob 52 is sized to slide along a longitudinal slot 53 formed in the housing 12. Projecting radially inwardly from a lower end of an inner surface 54 of the portion 50 is a locking rib 56, and an actuating rib 58. The locking rib 56 and actuating rib 58 project radially inwardly through the slot 40 formed in the interposer 22. The actuating rib 58 extends downwardly between the guide ribs 42 of the body 12, see Figs. 4 and 11.

The hammer 18, shown in Figs. 7 and 8, is longitudinally movable in the body 12, and includes a top wall 70 having an upper opening 72 to enable the handle 20 to be mounted therein. An upper portion 74 of the hammer 18 houses a coil compression spring 76 (see Fig. 3A) which serves as a recovery spring acting between the hammer and the handle 20, as will be explained. The lower portion of the hammer 18 comprises a latching arm 82, and a pair of parallel, longitudinal impact legs 80 which straddle the

guide ribs 42 of the body 12. The latching arm 82 is spaced from one of the legs 80, to accommodate the locking rib 56 therebetween (see Figs. 3A and 4). The latching arm 82 includes a radial outward finger 84 on its lower end, the top of which is defined by an inclined cam follower surface 86. As will be explained, the latching arm 82 is flexible in a radial direction when the finger 84 travels vertically past a stop 88 projection which projects radially inwardly from the inner surface of the housing 12 as the hammer is being raised to a cocked position (see Fig. 3E).

A coil compression spring 90 acts between an upper wall 92 of the body 12 and the top wall 70 of the hammer 18 to bias the hammer downwardly (see Fig. 3A). A coil compression spring 93 surrounding the spring 90 acts between the upper wall 92 and an upper edge 94 of the pusher 24 to bias the pusher downwardly.

The carrier unit 16 includes an adapter 100 depicted in Figs. 2 and 6. The adapter 100 is generally cylindrical and is telescopingly disposed within a stimulator sleeve 102. A coil compression spring 104 is interposed between a lower edge of the adapter 100 and an annular flange 106 projecting radially inwardly from an inner surface of the sleeve 102. The adapter 100 includes a plurality of longitudinal slots 107 dividing the adaptor into a plurality of spring fingers 108, two of which have a circumferential groove 110 formed in an upper portion thereof. The grooves are configured to receive projections 112 which are formed integrally on inner surfaces of the housing shells 12A, 12B, in order to releasably secure the adapter within the housing 12. That is, if a downward force is applied to the adapter, the spring fingers 108 will yield and permit the adapter to be removed from the housing 12.

The adapter 100 also includes three radially outwardly projecting keys 113 arranged to engage respective sides 114 of protrusions 115 formed on inner surfaces of the housing shells 12A, 12B. The keys 113 and sides 114 are oriented such that the adapter can only enter the housing 12 in one specific circumferential orientation. A longitudinal keyway 117 is formed in an inner surface of the adapter for reasons to be explained.

Telescopingly mounted within the sleeve 102 is an inner ring 116 having a radially outwardly projecting shoulder 118 near its lower end, and a radially inwardly projecting shoulder 120 formed near its upper end. The shoulder 118 is arranged to abut a lower end of the flange 106. The ring 116 includes an annular recess which receives a radial projection of the adapter 100 to form a snap-in connection 117 therebetween (see Fig. 2).

Situated coaxially within the adapter 100 and ring 116 is a lancet carrier 130 which is also depicted in Figs. 13-16. The lancet carrier 130 is generally in the form of a cylindrical sleeve which includes a vertical through-passage 131 to enable a disposable 150 to be inserted downwardly therein when the carrier unit 16 has been removed from the housing 12. A coil compression spring 132 acts between a radial outer flange 134 of the lancet carrier 130 and the radially inner shoulder 120 formed on the ring 116.

The lancet carrier includes a pair of downwardly inclined, upwardly facing guide ramps 140 formed on its inner surface for guiding the disposable. Lower ends of the guide ramps 140 intersect to form an upwardly open recess 142. The ramps and recess form an upwardly facing seat on which the disposable is supported. A radially outwardly projecting key 133 is formed on an upper annular flange 135 of the carrier 130. That key 133 enters the

keyway 117 of the adapter 100 to orient the carrier 130 circumferentially relative to the adapter.

The disposable 150 is depicted in Figs. 2 and 11 and includes a generally cylindrical body 152 having a
5 needle 154 projecting from its lower end. Projecting radially outwardly from an outer periphery of the disposable are three bosses 156 spaced circumferentially and longitudinally apart. That is, there are provided a lower boss 156, and a pair of upper bosses 158 disposed at
10 the same elevation above the lower boss. The three bosses are spaced circumferentially apart from one another as the disposable is viewed in a longitudinal direction. When the disposable is dropped downwardly into an upper end of the lancet carrier 130 (see Fig. 2), the two upper
15 projections engage respective ones of the two guide ramps 140 to guide downward motion of the disposable and ensure that the lower boss 156 enters the recess 142 (see also Fig. 13).

The disposable further includes a slot 160
20 extending longitudinally therealong. Disposed within the slot 160 are a plurality of pairs of opposed holding fingers 162 which are configured to frictionally grip the capillary tube 164 and retain the tube 164 in an orientation parallel to the longitudinal axis of the
25 disposable, as shown in broken lines in Fig. 11. Due to the cooperation between the projections 156, 158 of the disposable and the guide ramps 140 of the lancet carrier 130, the capillary tube will be positioned in axial alignment with the actuating finger 58 of the pusher 24
30 when the unit 16 is inserted into the housing 12, for reasons to be explained.

The handle 20 (Figs. 3A and 4) includes a pair of longitudinally extending lift fingers 170 which project downwardly through the top wall 70 of the hammer 18.
35 Lower ends of the lift fingers constitute radially

outwardly projecting feet 172 against which the lower end of the spring 76 bears. A manually grippable knob 174 is disposed at the top of the handle to enable a riser to raise the handle.

5 To explain the operation of the lancing device 10, attention is initially directed to Fig. 3A which depicts the device 10 in a condition where no disposable 150 is mounted in the carrier unit 16. To install a disposable, the carrier unit 16 is pulled downwardly from the housing,
10 and a disposable 150 is dropped downwardly into the carrier 130 (see Fig. 2). In so doing, the bosses 156, 158 of the disposable ride along the guide ramps 140 of the lancet carrier until the lower boss 156 comes to rest in the recess 142 of the carrier. As a result, the
15 capillary tube 164 of the disposable is oriented in a specific relationship with respect to the unit 16.

 The unit 16 is then pushed longitudinally upwardly into the front end of the housing 12 until the grooves 110 formed in the spring fingers 108 of the
20 adapter 100 snap onto the projections 112 of the housing 12, thereby locking the unit 16 in place (see Fig. 3B). Due to the relationship between the keys 113 on the adapter, and the sides 115 of the projections 114 formed on the housing 12, the adapter can be inserted in only
25 one circumferential (rotary) relationship relative to the housing 12. Furthermore, since the circumferential relationship between the lancet holder 130 and the adapter 100 is pre-set by the engagement between the key 133 on the holder 130 and the keyway 117 on the adapter, it is
30 ensured that the upper end of the capillary tube 164 is aligned with the actuating finger 58 of the pusher 24. Since the upper end of the capillary tube projects slightly upwardly past the upper end of the disposable 150 (see Fig. 3B), it pushes the actuating finger 58, and thus
35 the entire pusher 24, slightly upwardly. In so doing, the

locking rib 56 of the pusher is raised to a level above the stop 88 of the housing 12 for a reason which will become apparent.

5 If a protective sheath S covers the needle 154 (see Fig. 2), it can be pulled off by the user who then grasps the knob 174 of the handle 20 and pulls upwardly thereon (Fig. 3C). This causes the spring 76 to be compressed between the feet 172 of the raising fingers 170 on the one hand, and the top wall 70 of the hammer 18. 10 When the spring 76 bottoms out, further raising of the handle 20 causes the hammer 18 to be raised. Accordingly, the inclined surface 86 on the top of the latching finger 84 sequentially engages the undersides of the triggering protrusion 46 and the stop 88, causing the latching arm 82 15 to be flexed radially inwardly and allowing the finger 84 to pass over the protrusion 46 and then over the stop 88. Eventually, the finger 84 travels past the stop 88 and snaps radially outwardly, whereby downward movement of the finger (and thus of the hammer) is prevented by the top of 20 the stop 88 (Fig. 3C).

It will be appreciated that had the locking rib 56 not been previously raised, the latching finger could not have been flexed radially inwardly. Therefore, the locking rib 56 ensures that the hammer 18 cannot be placed 25 in an armed or cocked position unless a disposable 150 has been installed.

As the hammer 18 was raised, the spring 90 was simultaneously compressed, so now the hammer 18 is biased downwardly thereby.

30 When the handle 20 is released, the spring 76 pushes it downwardly (see Fig. 3D) until the feet 172 of the handle come to rest against a radially inwardly projecting shoulder 180 of the now-raised handle 18, whereby the knob 174 remains slightly raised by a distance

D with respect to its previous position, serving as a visual indication that the hammer is cocked (armed).

When the stimulating sleeve 102 is pushed downwardly against the user's skin (Fig. 3E), the sleeve 102 becomes displaced upwardly against the bias of the spring 104, and raises the interposer 22 and its triggering protrusion 46 against the bias of spring 45. The triggering protrusion 46 is circumferentially offset with respect to the stop 88, so the protrusion is able to contact the underside of the latching finger 84 and cam it radially inwardly off the stop 88. This enables the previously-compressed spring 90 to displace the hammer 18 and its impact legs 80 downwardly opposite the bias of the spring 76 and against the disposable 150 (Fig. 3F), to push the disposable 150 and the carrier 130 downwardly opposite the bias of the spring 132, whereby the needle lances the skin. The carrier 130 and the disposable 150 are immediately withdrawn upwardly by the action of the spring 132. Such withdrawal is possible since the hammer 18 was immediately retracted by the spring 76. Thus, the lancing and retraction of the lancet is performed as a substantially continuous motion.

Next, the user repeatedly reciprocates the housing 12 up and down, whereby the stimulating sleeve 102 remains in contact with the skin but is repeatedly pressured by the spring 45 and repeatedly opens and closes the wound in a manner pumping fluid (such as blood) to the skin surface in the manner described in greater detail in Application Serial No. _____ (attorney docket 018176-060), the disclosure of which is incorporated by reference herein.

That is, each time that a downward force is applied, the end face of the outer stimulating sleeve exerts a downward force which depresses a ring-shaped portion of the skin and body tissue which is disposed

in surrounding relationship to the wound or incision I, causing the wounded area to bulge while pulling apart the sides of the wound. Hence, fluid such as blood or interstitial fluid is trapped and pressurized so that it
5 travels upwardly through the pulled-open end of the bulging wound since the surrounding ring of depressed skin and body tissue restricts the outward flow of fluid.

When the downward force is released, the sides of the wound close, and fresh fluid flows toward the area of
10 the wound to replace fluid which had been forced upwardly through the wound. As the downward force is reapplied, the above-described action is repeated and additional fluid is forced through the wound. Eventually, this "pumping" action results in the formation of a suitably
15 large drop B of body fluid.

Although the end face of the sleeve 102 is disclosed as being generally annular, it could be of other configurations such as oval or polygonal, whereby the ring of depressed body tissue would be similarly configured.

20 When a sufficiently large drop of fluid B has been developed at the skin surface (Fig. 3G), the user applies a downward force F to the knob 52 of the pusher 24 to displace the pusher and its actuating rib 58 downwardly against the bias of the spring 38. This pushes the
25 capillary tube 164 downwardly until the lower end thereof projects from the bottom of the housing 12. At that point, the lower end of the capillary tube is placed in the drop of blood to draw blood thereinto by capillary action. The pusher 24 can be released, whereupon it will
30 be displaced upwardly by the spring 38.

Then, a strip of material 200 can be brought into contact with the bottom of the capillary tube (Fig. 3H) to draw-out the fluid sample for analysis.

To perform a subsequent lancing/sampling
35 operation, the user grasps the sleeve 102 and pulls out

the carrier unit 16. The disposable 150 can then be lifted from the carrier 130 and discarded, whereupon a new disposable can be inserted.

5 Except for the needle 154 and the springs 93, 90, 45, 76, 104 and 132, the parts of the lancing device 10 are preferably formed of plastic.

It will be appreciated that the device 10 provides for an automatic triggering of the hammer in response to a pressing of the device against the skin.
10 This eliminates any tendency for the user to jerk the device upwardly at the instant of triggering and ensures that penetrations of constant depth will be performed from one lancing operation to the next.

The ability of the device to prevent the hammer
15 from being cocked unless a disposable has been installed provides assurance that the disposable will not be accidentally displaced forwardly as the carrier unit is being installed, as could otherwise occur if the hammer were in a cocked state during such installation. Hence,
20 the user is protected against an accidental wounding.

The ability of the device to push-out the capillary tube for taking-in a fluid sample simplifies the sampling operation and minimizes the amount of direct manual handling of the capillary tube which is required.
25 In fact, no direct contact with that tube need occur when using the device. This feature of the invention does not require the use of a lancet for making the incision. In lieu of using a lancet to make an incision, known pneumatic or hydraulic injectors of the type which inject
30 pressurized gas or liquid against the skin could be used. Such auto injectors are sold by Becton-Dickinson, for example, to inject insulin. By eliminating the insulin and merely injecting the gas (e.g., air or nitrogen) or liquid (e.g., water) at pressures above 30 psi. an
35 incision could be formed in the skin for taking samples of

body fluid. Advantageously, small particles could be mixed with the gas to promote the tissue-cutting action. The particles could comprise carbon particles of from 1 micron to 0.010 inches in diameter.

5 The ability to load and unload a disposable into the carrier unit through an upper end of that unit means that the user can keep his/her hands remote from the needle. This ensures against accidental wounding, possibly by a contaminated needle. The three-point
10 securement of the disposable within the carrier, as defined by the three projections of the disposable, creates a stable movement-free mounting of the disposable within the carrier unit. Hence, the disposable will not tend to move laterally during a lancing procedure, thereby
15 reducing the amount of pain that may be experienced by the user.

 Also, as explained in concurrently filed application Serial No. _____ (attorney docket 018176-060), the ability of the device to pump body fluids such as
20 blood or interstitial fluid to the skin surface enables the device to be used to lance the skin at areas of the body which are less susceptible to pain, such as the arm for example.

 Although the present invention has been described
25 in connection with a preferred embodiment thereof, it will be appreciated by those skilled in the art that additions, modifications, substitutions and deletions not specifically described may be made without departing from the spirit and scope of the invention as defined in the
30 appended claims.

CLAIMS:

1. A lancing device for lancing the skin to sample blood or interstitial fluid, comprising:

a housing;

5 a lancet carrier adapted to hold a disposable lancet, the carrier mounted adjacent a front end of the housing for movement relative thereto;

10 a cockable spring-biased hammer mechanism for displacing the lancet carrier forwardly to lance the skin;

a latch for releasably retaining the hammer mechanism in a cocked position; and

15 a latch-releasing mechanism including a skin-contacting portion for being rearwardly displaced in response to being pressed against the skin, and a latch-releasing portion for releasing the latch in response to the rearward displacement of the skin-contacting portion.

20 2. The lancing device according to claim 1 wherein the skin-contacting portion comprises a sleeve mounted at the front end of the housing, the sleeve being spring-biased forwardly and being displaceable rearwardly in response to being pressed against the skin, to cause the latch-releasing portion to release the latch.

3. The lancing device according to claim 1, further comprising a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

4. The lancing device according to claim 3, wherein the lancet carrier carries a disposable lancet which includes a body having a skin-lancing member and a capillary tube, and further including a manually actuable pusher member for pushing the capillary tube forwardly relative to the carrier for drawing-in fluid from the lanced skin, the safety device being moved to its non-safety position by an upper end of the capillary tube.

5. The lancing device according to claim 4, wherein the lancet carrier comprises a sleeve mounted in the housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; a disposable lancet seated in the through-passage; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

6. The lancing device according to claim 1, wherein the lancet carrier carries a disposable lancet which includes a body having a skin-lancing member and a capillary tube, and further including a pusher member for pushing the capillary tube forwardly relative to the carrier for drawing-in fluid from lanced skin.

7. The lancing device according to claim 1,
wherein the lancet carrier comprises a sleeve mounted in
the housing; the sleeve including an internal surface
forming a through-passage extending from an upper end to a
5 lower end of the sleeve; a disposable lancet seated in the
through-passage; the internal surface configured to permit
insertion and removal of the disposable lancet solely
through the upper end; the internal surface including at
least one upwardly facing seat on which the disposable
10 lancet is supported.

8. The lancing device according to claim 3,
wherein the lancet carrier comprises a sleeve mounted in
the housing; the sleeve including an internal surface
forming a through-passage extending from an upper end to a
15 lower end of the sleeve; a disposable lancet seated in the
through-passage; the internal surface configured to permit
insertion and removal of the disposable lancet solely
through the upper end; the internal surface including at
least one upwardly facing seat on which the disposable
20 lancet is supported.

9. The lancing device according to claim 6,
wherein the lancet carrier comprises a sleeve mounted in
the housing; the sleeve including an internal surface
forming a through-passage extending from an upper end to a
25 lower end of the sleeve; a disposable lancet member seated
in the through-passage; the internal surface configured to
permit insertion and removal of the disposable lancet
member solely through the upper end; the internal surface
including at least one upwardly facing seat on which the
30 disposable lancet member is supported.

10. The lancing device according to claim 1 wherein the skin contacting portion includes a sleeve structure mounted for repeated rearward displacements to urge body fluid from lanced skin.

5 11. The lancing device according to claim 10 wherein the skin contacting portion is shaped to form a depressed ring of body tissue in surrounding relationship to an incision formed in the skin.

10 12. The lancing device according to claim 11 wherein the lancet carrier carries a disposable element having a skin-lancing member, and a capillary tube for drawing-in body fluid from an incision.

15 13. The lancing device according to claim 12, further including a pusher for pushing the capillary tube downwardly relative to the carrier.

20 14. The lancing device according to claim 13, further including a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position by a rear-end of the capillary tube.

25 15. The lancing device according to claim 11, further including a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

16. A lancing device for lancing skin to sample blood or interstitial fluid, comprising:

a housing;

5 a lancet carrier adapted to carry a disposable lancet and installable into a front end of the housing and being movable relative thereto;

a cockable spring-biased hammer mechanism for displacing the lancet carrier forwardly to lance the skin;

10 a latch-releasing mechanism for releasing the latch; and

15 a safety device normally disposed in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position in response to installation of the lancet carrier into the housing for enabling the hammer mechanism to be cocked.

17. The lancing device according to claim 16, wherein the lancet carrier carries a disposable lancet which includes a body having a skin-lancing member and a capillary tube, and further including a pusher member for pushing the capillary tube forwardly relative to the carrier for drawing-in fluid from the lanced skin.

20

18. The lancing device according to claim 17,
wherein the lancet carrier comprises a sleeve mounted in
the housing; the sleeve including an internal surface
forming a through-passage extending from an upper end to a
5 lower end of the sleeve; the internal surface configured
to permit insertion and removal of the disposable lancet
solely through the upper end; the internal surface
including at least one upwardly facing seat on which the
disposable lancet is supported.

10 19. The lancing device according to claim 16,
wherein the lancet carrier comprises a sleeve mounted in
the housing; the sleeve including an internal surface
forming a through-passage extending from an upper end to a
lower end of the sleeve; a disposable lancet seated in the
15 through-passage; the internal surface configured to permit
insertion and removal of the disposable lancet solely
through the upper end; the internal surface including at
least one upwardly facing seat on which the disposable
lancet is supported.

20 20. A lancing device for lancing skin to sample
blood or interstitial fluid, comprising:

a housing;

25 a carrier carrying a disposable lancet, the
disposable member including a body having a skin-
lancing member and a capillary tube;

a spring-biased hammer for pushing the carrier forwardly so that the lancet lances the skin; and

a pusher member for pushing the capillary tube forwardly relative to the carrier for drawing-in fluid from lanced skin.

5

21. The lancing device according to claim 20, wherein the carrier comprises a sleeve mounted in the housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

10

15

22. In combination, a disposable lancet and a carrier therefore; the carrier comprising a sleeve adapted to be mounted in a housing; the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve; the disposable lancet seated in the through-passage; the internal surface configured to permit insertion and removal of the disposable lancet solely through the upper end; the internal surface including at least one upwardly facing seat on which the disposable lancet is supported.

20

25

23. The combination according to claim 22 wherein the seat includes a plurality of the upwardly facing shoulders, the lancet including vertically spaced projections extending outwardly therefrom and bearing against respective ones of the upwardly facing shoulders.

24. The combination according to claim 23 wherein the upwardly facing shoulders comprise a pair of downwardly inclined ramps and a slot disposed below the ramps.

5 25. A lancet carrier adapted to carry a disposable lancet, the lancet carrier comprising a sleeve adapted to be mounted in a housing, the sleeve including an internal surface forming a through-passage extending from an upper end to a lower end of the sleeve and
10 configured to permit insertion and removal of a disposable lancet solely through the upper end, the internal surface including an upwardly facing seat adapted to support a disposable lancet.

15 26. A sampling device for sampling body fluid, comprising:

a housing defining a longitudinal axis;

incision-forming means mounted in the housing for forming an incision through a skin surface;

20 a stimulator member mounted at a forward end of the housing and being depressible against the skin to depress a ring of body tissue in surrounding relationship to the skin for urging body fluid toward and outwardly through the incision to form a drop of body fluid at an open
25 end of the incision; and

a pusher member for moving the capillary tube forwardly relative to the lancet carrier for drawing-in the body fluid.

27. The lancing device according to claim 26 wherein the incision forming means comprises:

5 a lancet carrier carrying a disposable lancet, the lancet including a skin-lancing member and a capillary tube, the lancet carrier mounted adjacent a front end of the housing for longitudinal movement relative thereto; and

10 means for driving the lancet carrier forwardly and then rearwardly in a substantially continuous motion to form an incision through the skin surface and retract the lancet from the incision.

28. The lancing device according to claim 27, further including a cockable spring biased hammer mechanism in the housing for displacing the lancet carrier
15 forwardly; and a safety device disposed in the housing normally in a safety position for preventing the hammer mechanism from being cocked, and being movable to a non-safety position by a rear end of the capillary tube.

29. A method of taking a sample of body fluid,
20 comprising the steps of:

A) abutting a forward end of a housing against a skin surface of a user's body;

B) forming an incision through the skin surface;

25 C) pressing the housing against the skin surface to repeatedly depress a ring of body tissue in surrounding relationship to the incision to urge body fluid toward and outwardly through the

30.

incision to form a drop of body fluid at an open end of the incision;

D) extending the capillary tube forwardly relative to the carrier; and

5 E) inserting a forward end of the capillary tube into the drop of body fluid to draw-in the body fluid.

10 30. The method according to claim 29 wherein step A comprises abutting the housing against a surface of the user's body other than a finger tip thereof.

31. The method according to claim 29 wherein step A comprises abutting the housing against the user's forearm.

1/11

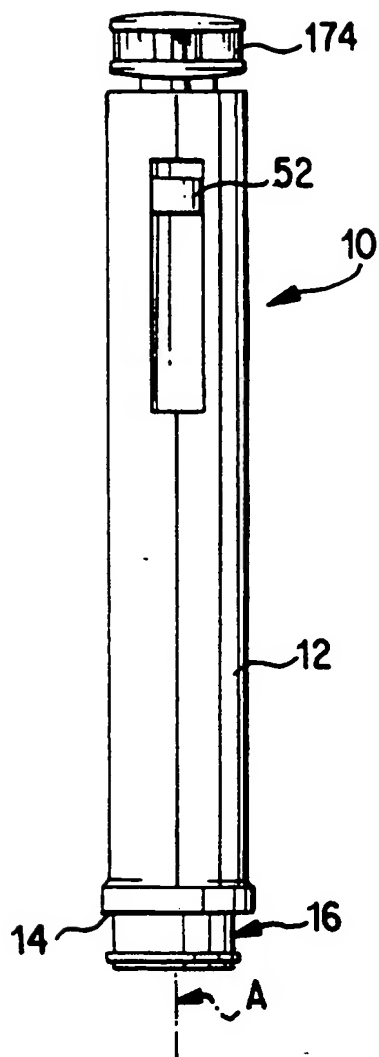


FIG. 1

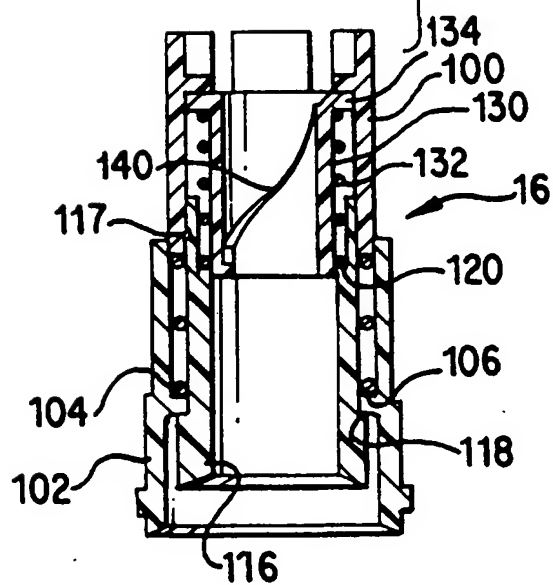
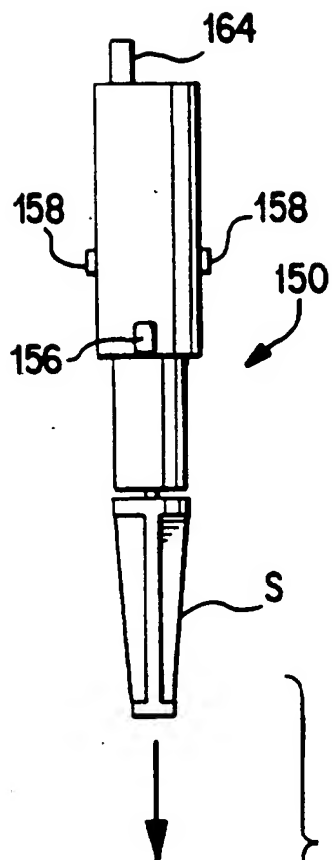


FIG. 2

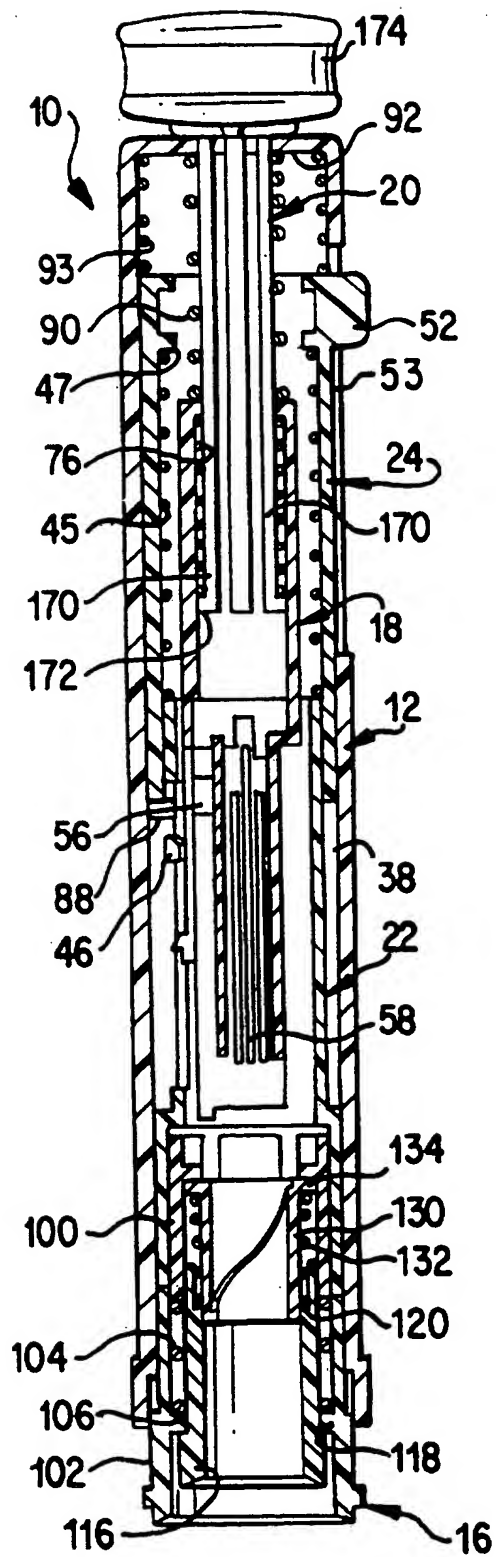


FIG. 3A

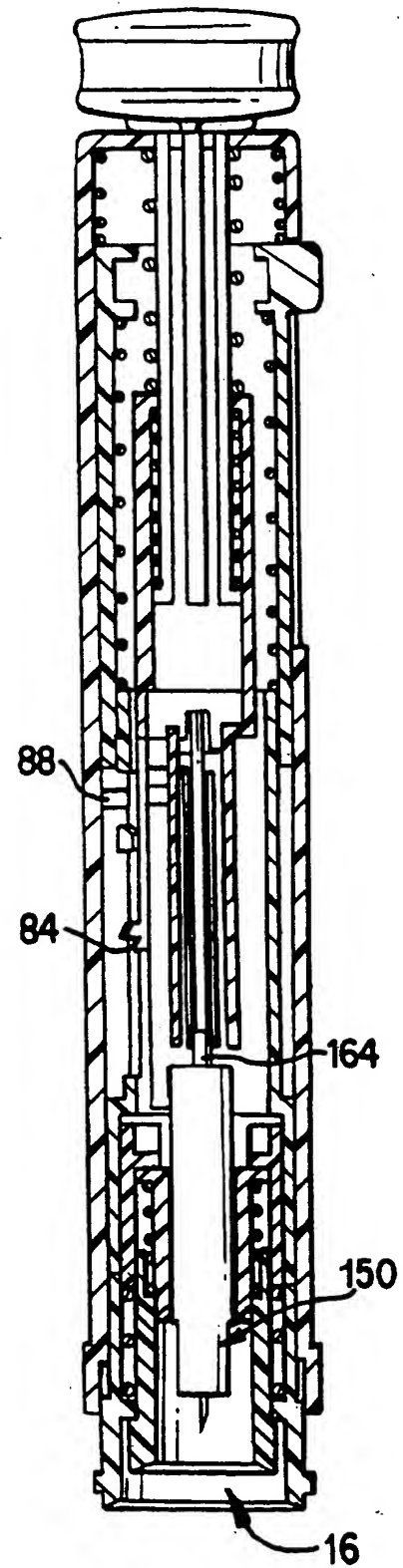


FIG. 3B

3/11

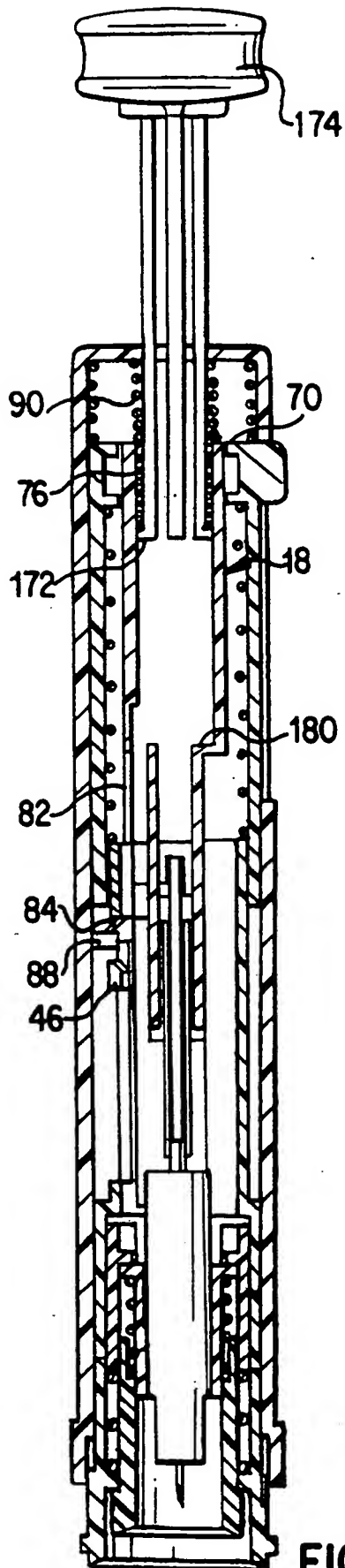


FIG. 3C

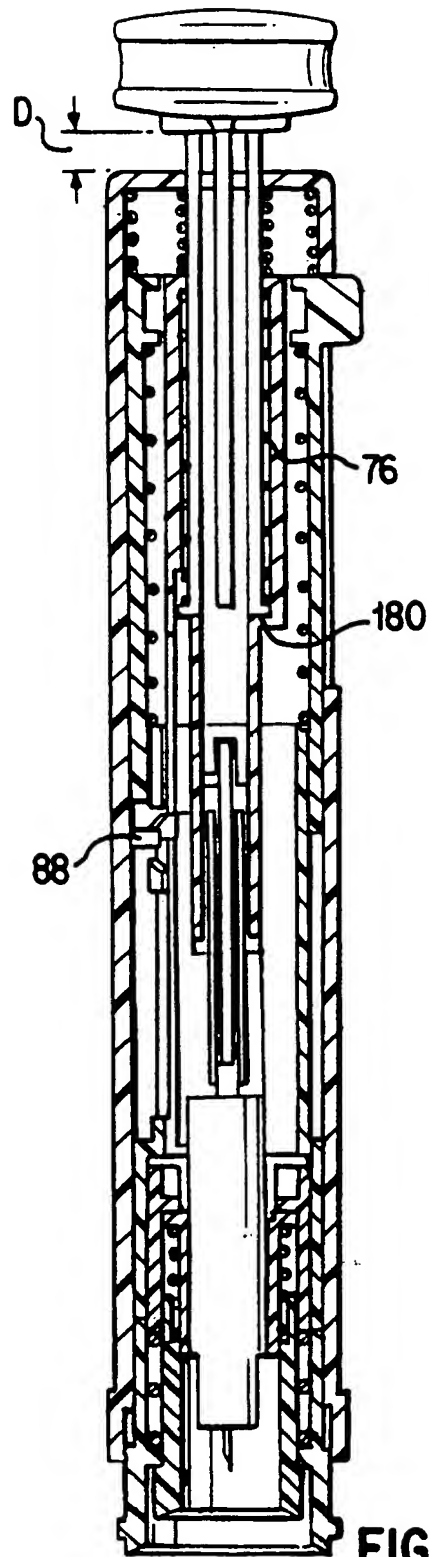


FIG. 3D

4/11

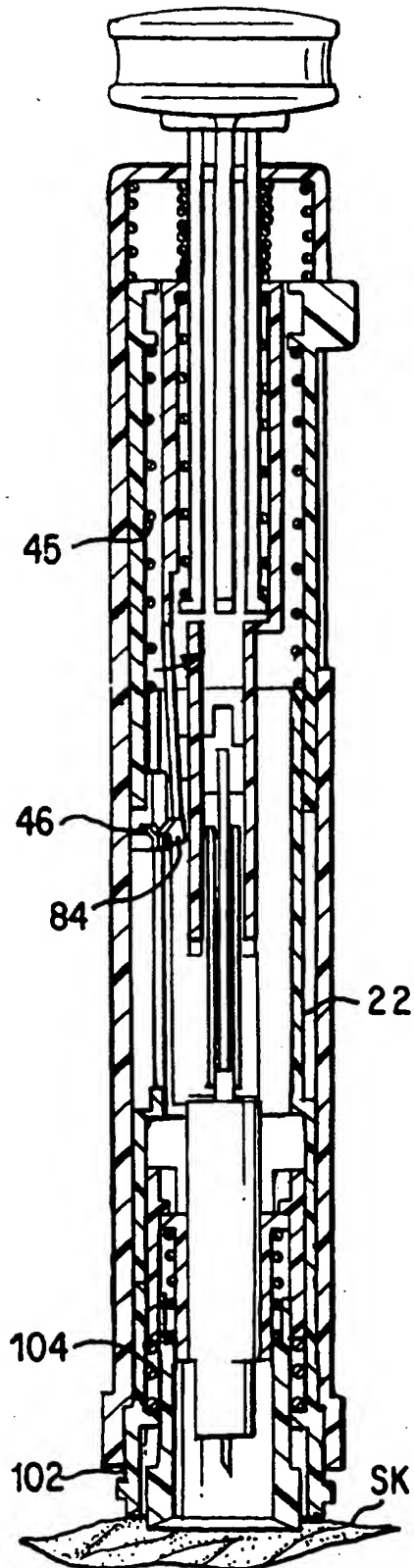


FIG. 3E

SUBSTITUTE SHEET (PILL E 26)

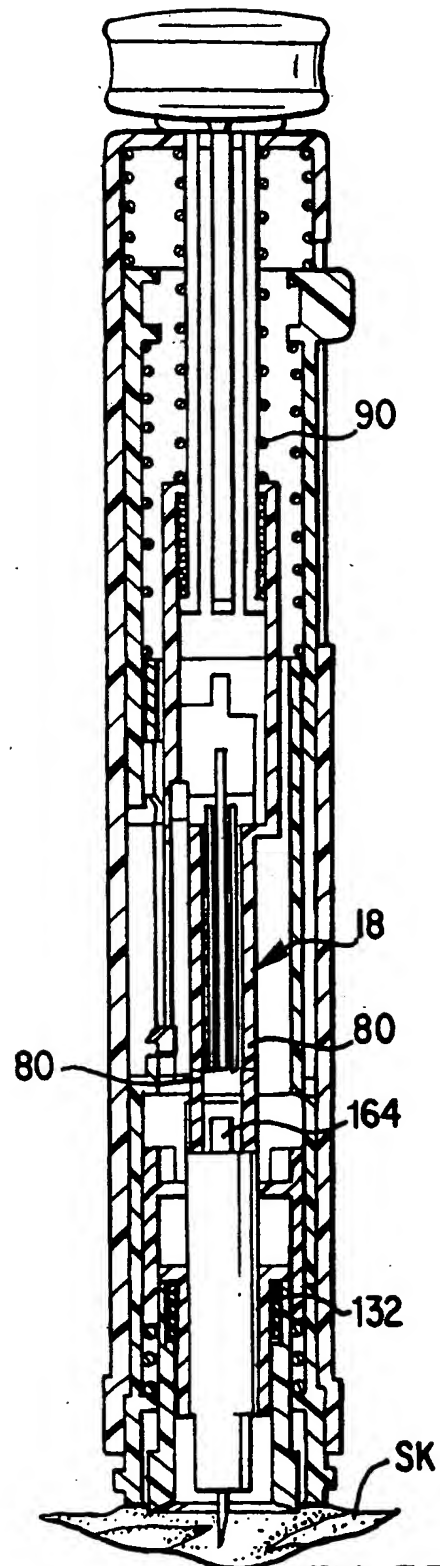
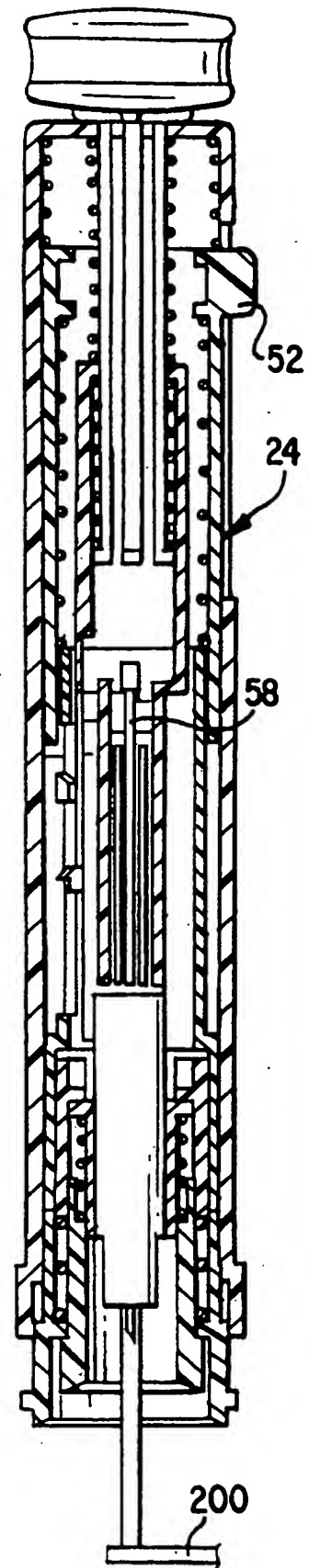
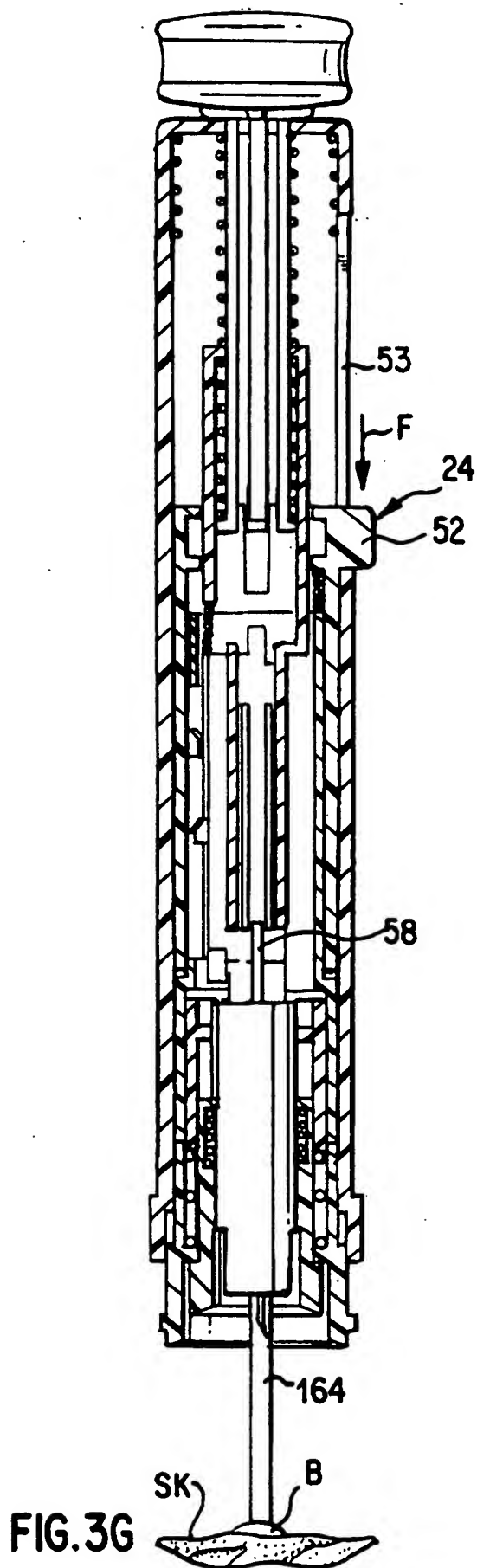


FIG. 3F

5/11



6/11

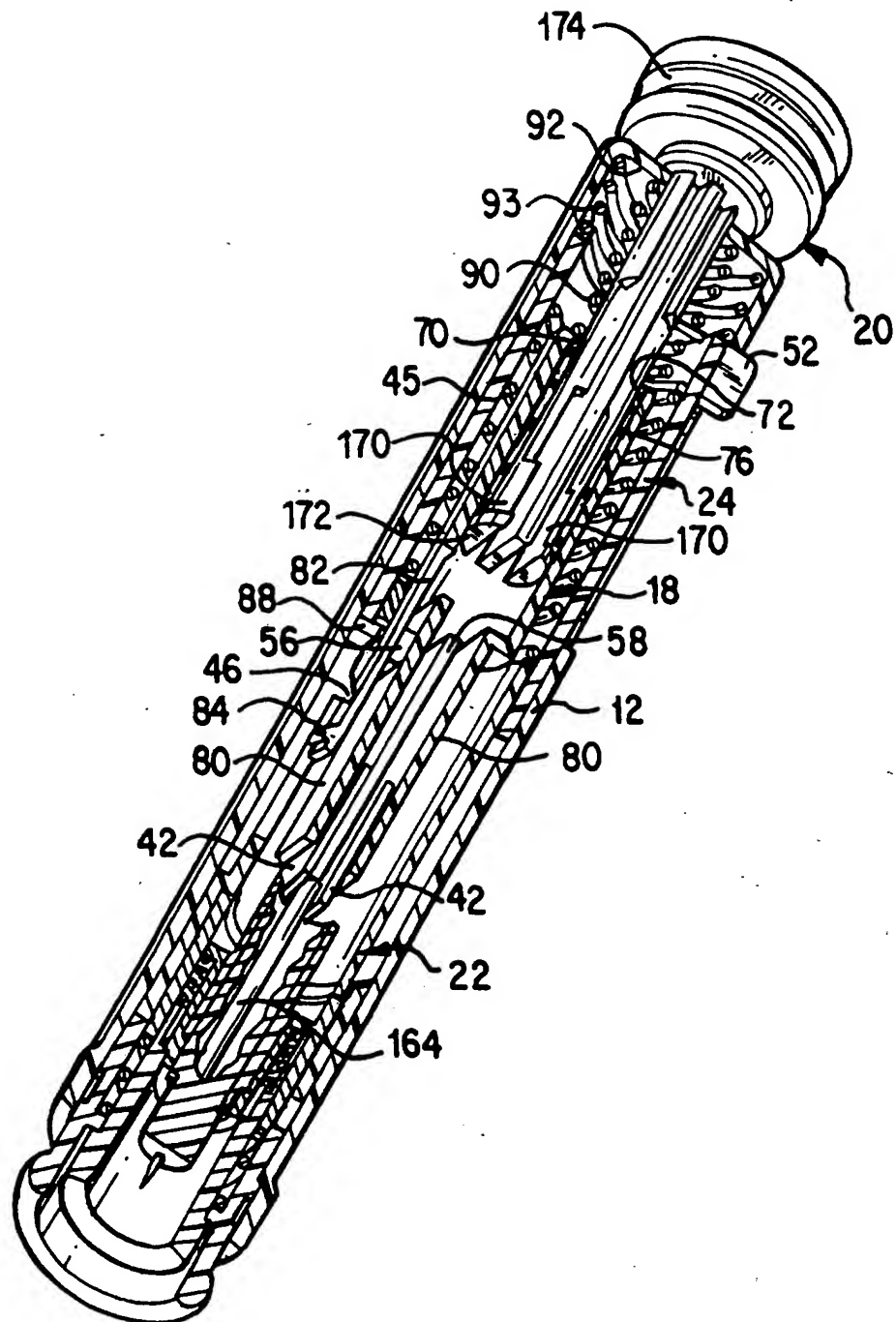


FIG. 4

7/11

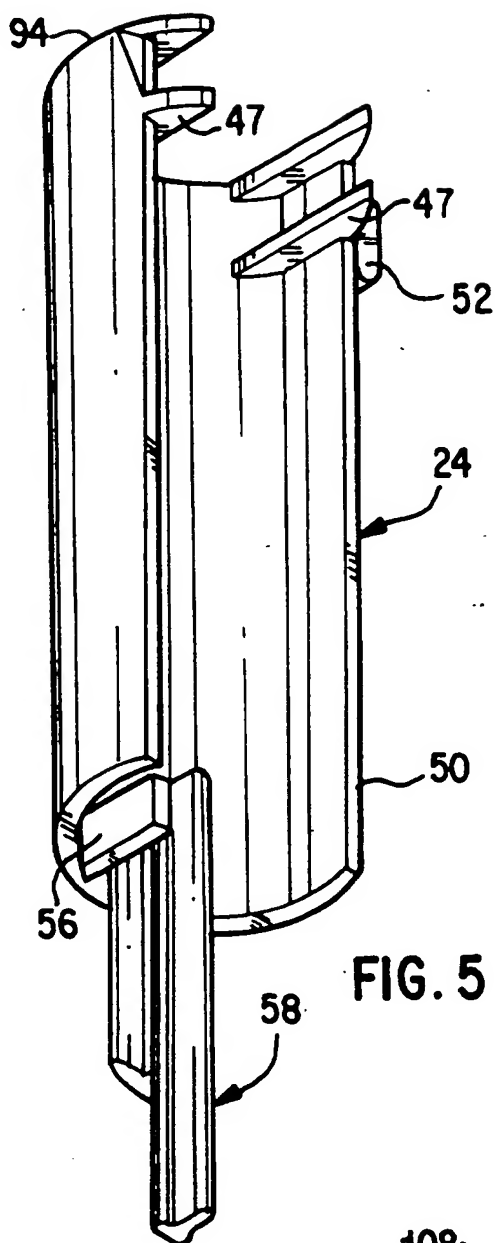


FIG. 5

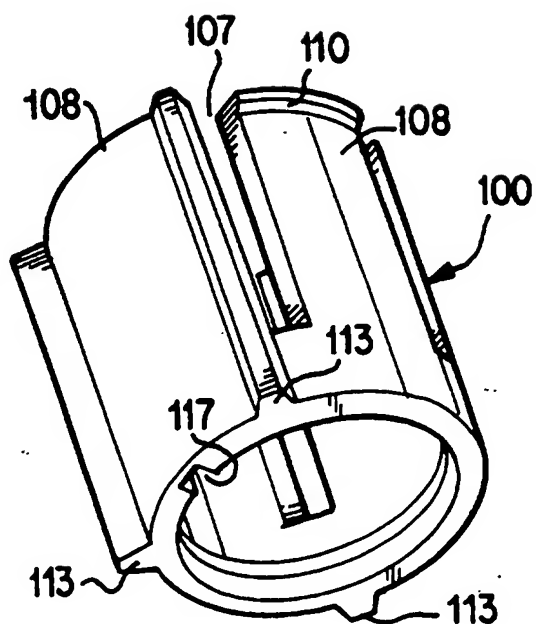


FIG. 6

8/11

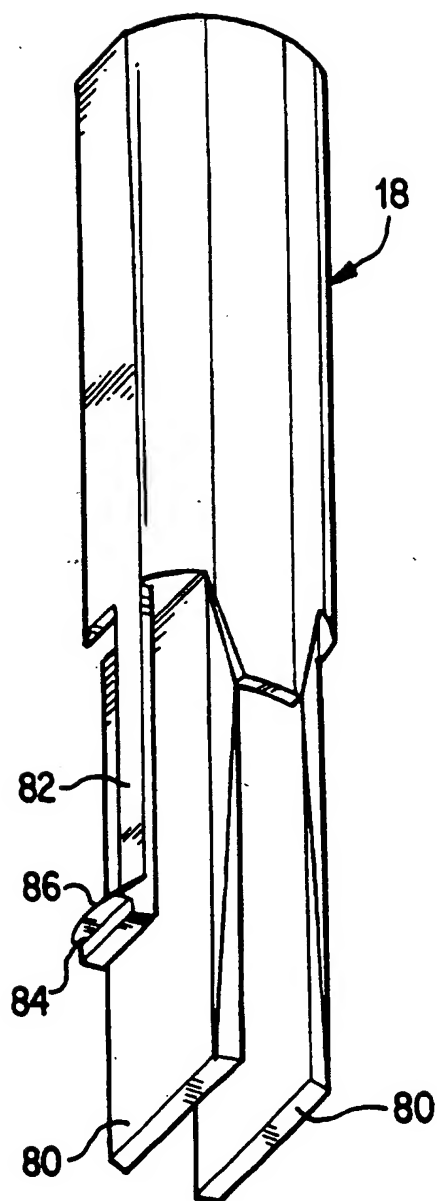


FIG. 7

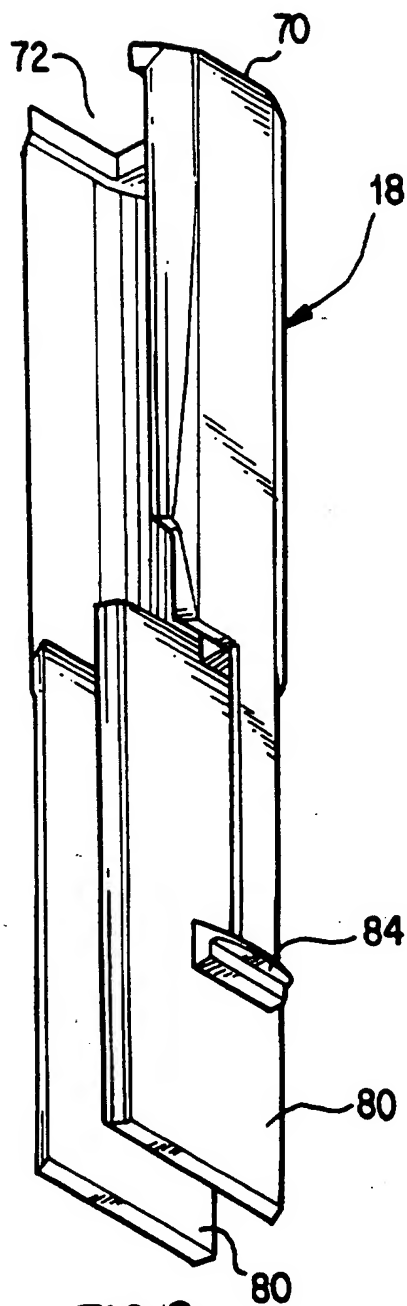


FIG. 8

9/11

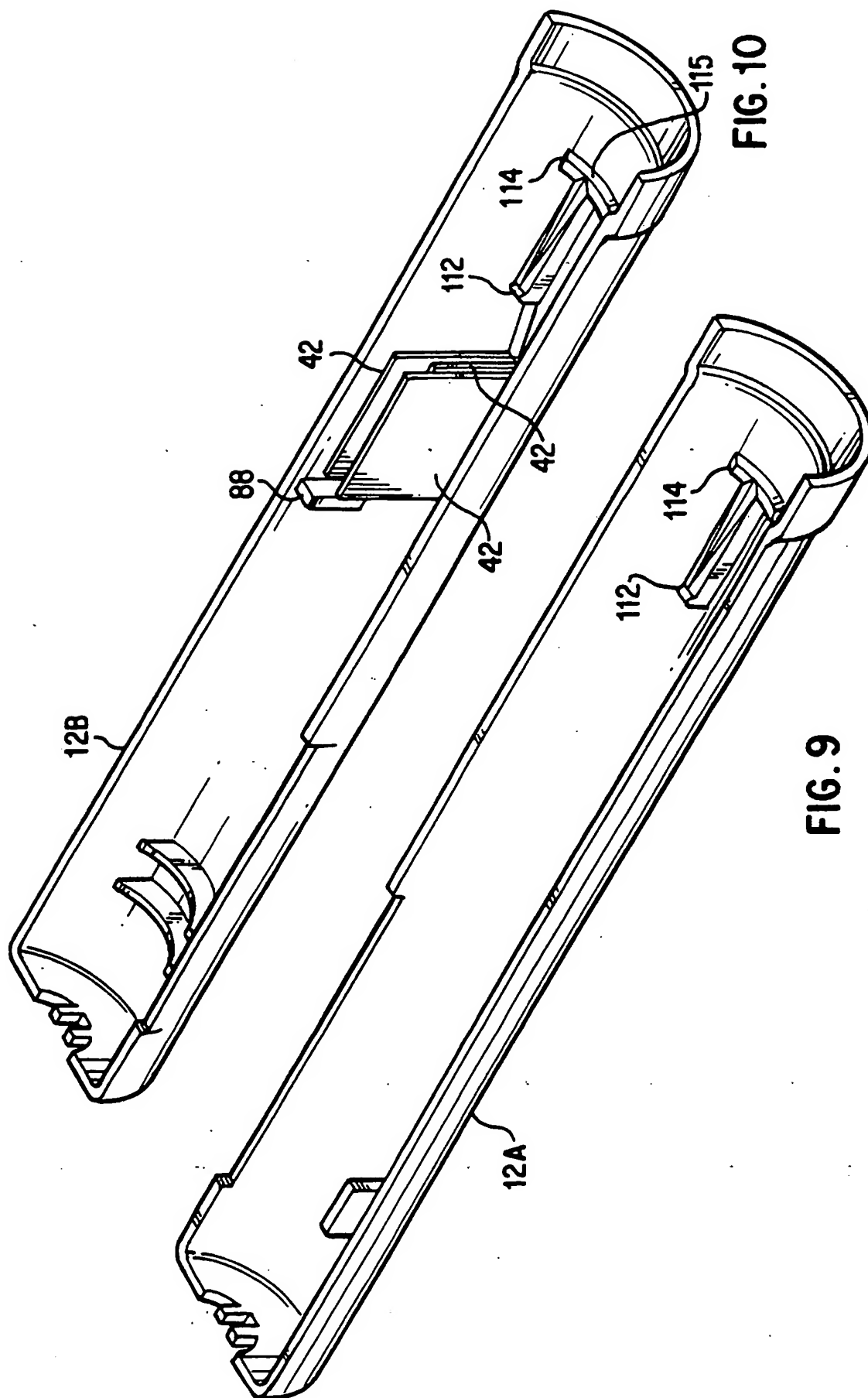


FIG. 10

FIG. 9

10/11

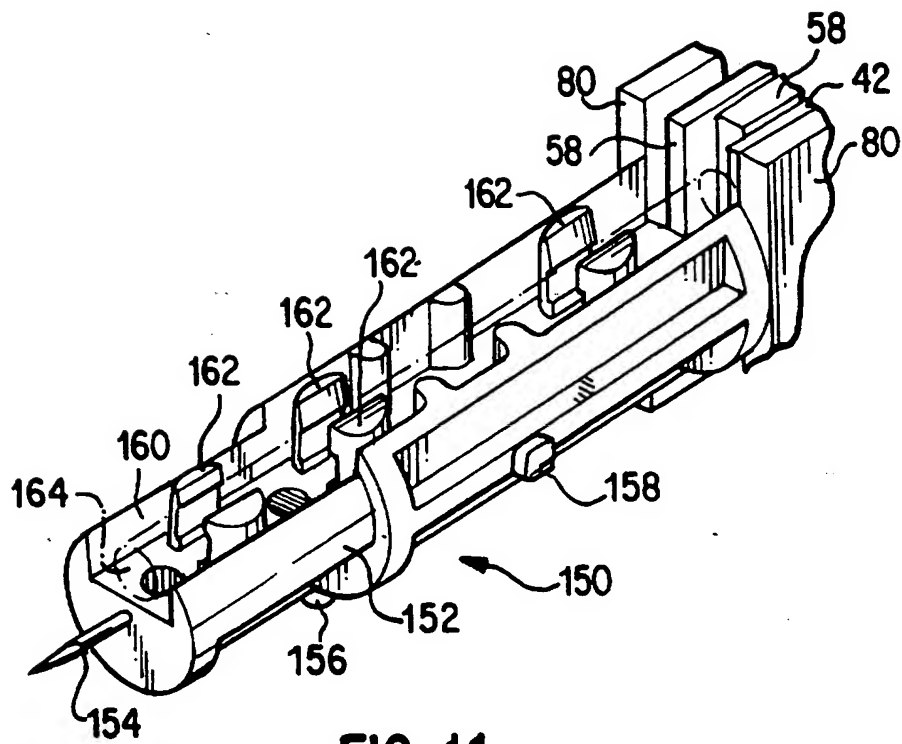


FIG. 11

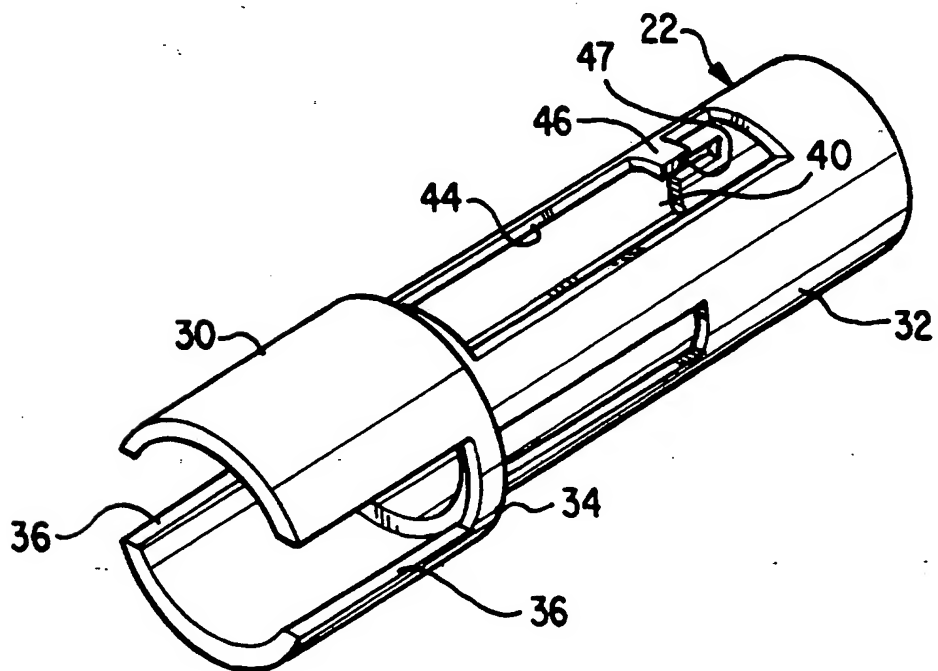


FIG. 12

11/11

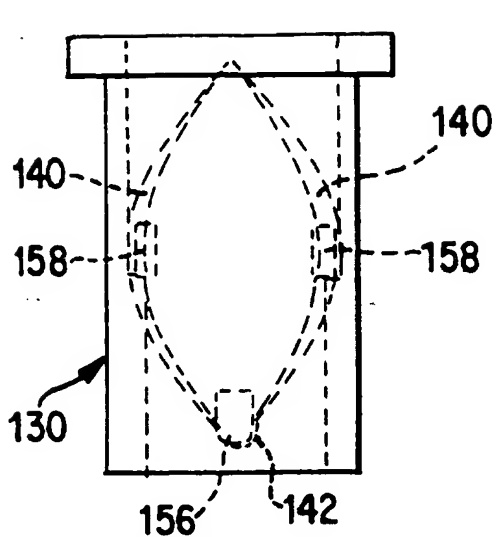


FIG. 13

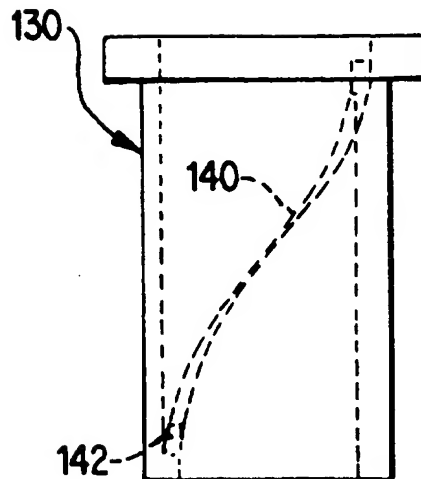


FIG. 14

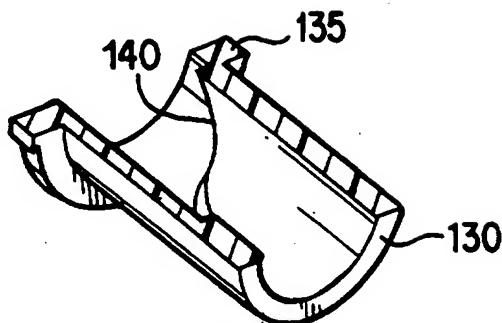


FIG. 15

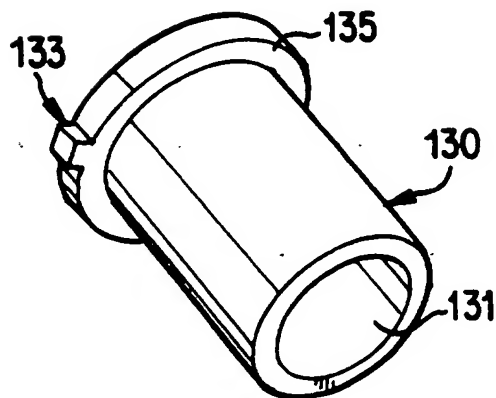


FIG. 16

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/08402

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61B 17/32

US CL : 606/181

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/181, 182, 760, 765, 766, 770

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,869,249 A (CROSSMAN et al) 26 September 1989, col. 3, lines 7-21.	1
X	US 4,844,095 A (CHIODO et al) 04 July 1989, entire document.	1, 2, 7
X, P	US 4,660,570 A (DOMBROWSKI) 28 April 1987, entire document.	20
X	US 4,976,724 A (NIETO et al) 11 December 1990, col. 2, lines 36-41.	22, 23, 25
X	US 3,626,929 A (SANZ et al) 14 December 1971, entire document.	26, 27, 29
---		-----
Y		30, 31

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
* A	document defining the general state of the art which is not considered to be of particular relevance		
* E	earlier document published on or after the international filing date	* X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* L	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* Y	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* O	document referring to an oral disclosure, use, exhibition or other means		
* P	document published prior to the international filing date but later than the priority date claimed	* A	document member of the same patent family

Date of the actual completion of the international search

31 JULY 1997

Date of mailing of the international search report

05 SEP 1997

 Name and mailing address of the ISA/US
 Commissioner of Patents and Trademarks
 Box PCT
 Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

TINA T. D. PHAM

Telephone No. (703) 308-0824